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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/305,738	05/06/1999	KLAUS MOSBACH	003300-357	2570

7590 05/05/2003

MORGAN & FINNEGAN LLP
345 PARK AVENUE
NEW YORK, NY 10154

EXAMINER

CEPERLEY, MARY

ART UNIT	PAPER NUMBER
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1641

25

DATE MAILED: 05/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/305,738

Applicant(s)

MULLER ET AL.

Examiner

Mary (Molly) E. Ceperley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-45 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 27-45 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 6) ☐ Other: _____

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1) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2) The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3) Claims 42-45 are rejected under 35 U.S.C. 112, first paragraph, as **a)** containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention and **b)** as being based on a specification which does not contain an adequate written description of how to use the claimed invention. There does not appear to be any description in the specification of the antibodies of claim 42 which are "solubilized or suspended in a liquid". The specification also fails to set forth a utility for antibodies "solubilized or suspended" in mammalian body fluids.

^{27,28}
3) Claims ~~28, 29~~, and 34-45 are rejected under 35 USC 112, first paragraph, as being based on a specification which fails to provide an adequate enabling written description to support the scope of the claimed invention. The specification fails to describe the use of print molecules other than drugs which would be useful to prepare artificial antibodies "having specific binding sites" useful in immunoassays. The claims include, for example, metals or metal complexes used as print molecules which would not be expected to have the disclosed immunoassay utility.

4) The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5) Claims 37 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 37 and 38, drawn to "antibodies" are improperly dependent from claim 34 which is drawn to "a method for assaying a drug molecule".

6) Claims 39-45 are rejected under 35 USC 112, second paragraph, as being indefinite and confusing for the reason that the claim limitations of "biocompatible" and "have a particle size of less than about five microns" appear to be redundant since the "particle size of less than about five microns" is stated to be a requirement for "biocompatibility" (specification, page 4, lines 21-25).

7) Claims 27, 28, and 34-45 are rejected under 35 USC 112, second paragraph, as being indefinite and incomplete in not reciting the moiety which is used in the "molecular imprint polymerization" method to form the "artificial antibody". In the absence of the recitation of the type of molecule to be imprinted, the type of "specific binding sites" intended is unclear.

8) Claims 34 and 35 are rejected under 35 USC 112, second paragraph, as being indefinite and confusing for the reason that the "artificial antibodies of according to claim 27" recited in claim 34 are not limited to antibodies produced using "a drug molecule". Thus, claims 34 and 35 do not require the use of "artificial antibodies" which are specific for the "drug molecule" being assayed.

9) Claims 27-45 are rejected under the judicially created doctrine of double patenting over the corresponding claims of U.S. Patent No. 5,959,050 for the reasons of record stated in the Office action of

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August 07, 2001. Applicants' stated intention of filing a terminal disclaimer upon the allowance of the claims of this application is noted.

10) Claims 27-45 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mosbach (U.S. 5,110,833) for the reasons of record as stated in the Office action of August 07, 2001.

Applicants' arguments filed December 12, 2002 have been fully considered but they are not persuasive. Applicants cite the O'Shannessy references which are referenced at col. 5, lines 30-33 of Mosbach (see form PTO-892 attached) in support of the argument that Mosbach teaches away from the claimed particle size range (Remarks, page 4). However, contrary to applicants' assertion that O'Shannessy et al discard particles less than 25 microns in diameter, at page 393 of the reference, these particles were "slurried by sonication in water-acetonitrile-acetic acid...and packed" into a column thus indicating that this particle size range was considered to be useful (see O'Shannessey et al (I), the first paragraph under *High-performance liquid chromatography*). The same disclosure appears at page 145 of O'Shannessey et al (II). Since the "biocompatible" limitation of claim 39 is considered to be redundant with the "particle size of less than about five microns" claim limitation (specification, page 4, lines 21-25), claim 39 is also considered to be properly rejected over Mosbach for the reasons of record.

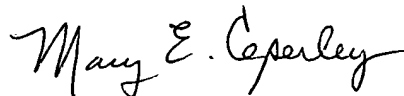
11) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. (Molly) Ceperley whose telephone number is (703) 308-4239. The examiner can normally be reached from 8 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached at (703) 305-3399. The fax phone number for responses to be filed BEFORE final rejection is (703) 872-9306. The fax phone number for responses to be filed AFTER final rejection is (703) 872-9307.

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Questions which are NOT RELATED TO THE EXAMINATION ON THE MERITS, should be directed to **TC 1600 CUSTOMER SERVICE** at **(703) 308-0198**. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

May 02, 2003



Mary E. (Molly) Ceperley
Primary Examiner
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